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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,195	09/12/2000	Howard R. Levin	3659-17	6619

7590 07/03/2002

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/03/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,195

Applicant(s)

LEVIN ET AL. *Ch*

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 7 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,5,6</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "403" has been used to designate two different sections of the drawing in FIG 10. The specification does not allude to a missing portion of FIG 10, but the double-numbering is confusing. Examiner suggests a single reference numeral with two lines that point to different structures, if that was the illustration intended by applicant. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 7 is objected to because of the following informalities: Please remove "that" from line 3 of the claim. Appropriate correction is required.

3. Claim 13 is objected to because the use of the word "form" in line 2 is ambiguous. It is unclear whether applicant intends the word "form" as a noun to further define the shape housing or as a verb (formed) to describe the composition of the housing relating to the biocompatible material.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,679,245 to Manica. Manica discloses an extracorporeal treatment apparatus with flow circuits and pressure sensors. The flow circuit takes blood from the patient via catheter 33, through line 34, and returns treated blood to the patient via line 35 to catheter 36 (see FIG 2). The withdrawal catheter may be inserted into an artery or a vein of the patient, and the return catheter is inserted into a vein, making it possible for the draw and return of blood to occur within the same patient vessel (column 3, lines 61-67, column 4, lines 1-4). The flow circuit includes several roller pumps (52, 66, 78, 84) that draw fluid through the system, a filtration unit 40 with a conventional semipermeable membrane 42 (column 4, lines 5-10, FIGS 1, 2). The pressure sensors are located in the blood inlet line (51), the blood outlet line (53), and in the filtration fluid circuit (54) (column 4, lines 5-57, column 5, lines 47-60, FIG 2). Manica discloses that the pressure sensors send electrical signals that correspond to the measured pressure via a multiplexer 150 and an analog-digital converter 152 to a monitor processor 140.
6. With regard to applicant's recitation of a "cartridge," Webster's Collegiate Dictionary (2001) defines a cartridge as "a case or container that holds a substance, device, or material which is difficult, troublesome, or awkward to handle and that usually can be easily changed." As such, it is examiner's position that a cartridge includes any of the tubing, clamps, filter housing, and connectors through which fluid may pass during a fluid processing procedure.

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7. As to applicant's limitations drawn to the disposable and detachable nature of the claimed invention, it is examiner's position that any equipment is capable of being disposed or thrown away, and any equipment is capable of being detached from an operating apparatus or pumping system. Those limitations do not add any patentable weight to the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5, 6, 10, 11, 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,679,245 to Manica in view of US 6,171,253 to Bullister et al. Manica discloses the apparatus as claimed with the exception of the pressure sensors having a tubular shape, mounted within the blood channel. Bullister discloses a flow-through pressure sensor in order to precisely measure fluid pressure in a chamber without affecting the flow of fluid through the chamber. The sensor 18 is attached to a flow vessel, and includes a hemocompatible cannula tube 30 through which the fluid is channeled (column 2, lines 31-39, 60-64, FIGS 1 and 2). The pressure sensor further includes a diaphragm 34 that is displaced according to the fluid pressure within the flow passage. The flexing of the diaphragm is measured by strain gauges 42 that produce an electrical voltage signal as the diaphragm is deformed under varying amounts of

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pressure (column 3, lines 16-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to employ the flush-mounted flow through pressure sensors disclosed by Bullister in the extracorporeal blood processing system disclosed by Manica in order to measure the pressure of the fluid flowing through the passageways without disturbing actual fluid flow, as taught by Bullister.

10. Furthermore, there are no size limits directed to the pressure sensor disclosed by Bullister, and the pressure sensor may be adapted to measure the pressure within a cylindrical blood filter, such as that disclosed by Manica. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to adapt the pressure sensor disclosed by Bullister to measure the pressure of blood flowing through the filter in the system disclosed by Manica.

11. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,679,245 to Manica in view of US 6,171,253 to Bullister et al in view of US 4,229,299 to Savits et al. The modified Manica device discloses the apparatus as claimed with the exception of transparent blood passages and the pressure sensor embedded in the filter. Savits discloses a pump means for dialysis treatment with tubing that forms blood passageways and a filtration device. The use of transparent tubing for blood processing machines is well known in the art of extracorporeal blood treatment, and is incorporated in the Savits device (column 8, lines 32-35). Therefore, it would have been obvious to one of ordinary skill in the art to provide the modified Manica extracorporeal blood processing device with conventional transparent tubing in order to monitor the flow of blood through the system. Furthermore, Savits discloses the use of a

hollow-fiber blood filter, which is well known in the art of blood treatment, and allows for removal of impurities from the blood (column 5, lines 4-7). The tubular pressure sensor disclosed by Bullister is capable of measuring fluid through any tubular conduit, and may be reduced in size in order to be incorporated within the hollow fiber of a semipermeable filter in order to measure the pressure of the dialysate fluid flowing within the hollow fibers of the Savits blood filter. Therefore, it would have been obvious to one of ordinary skill in the art to use the hollow fiber filter disclosed by Savits in the modified Manica device in order to allow the tubular pressure sensor disclosed by Bullister to measure the pressure of the fluid flowing through the filtration fluid side of the blood processing circuit, without adversely affecting the flow thereof, as taught by Bullister.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 4,436,620 Bellotti et al
 - i. Hydraulic fluid circuit for use in hemodialysis
- b. US 5,410,916 Cook
 - ii. Flow-through pressure sensor
- c. US 5,756,900 Arie et al
 - iii. Pressure sensing apparatus for tubular conduit

d. US 6,272,930


Crozafon et al

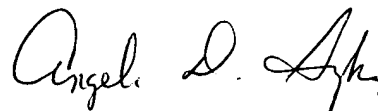
iv. Tube assembly with pressure measuring device

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

lrd 
June 25, 2002



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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